HOLD TIME PROTOCOL

FOR

TELMISARTAN TABLETS

PROTOCOL EFFECTIVE DATE	:	
TOTAL PAGE No.	:	09

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1.0 Pre-approval Protocol:

Signing of this approval page of hold time study for protocol indicates agreement with the approach described in this document. If modifications to the approach become necessary; an addendum will be prepared and approved.

Prepared By	**Signature**	**Date**
(Quality Assurance)		

Checked By	**Signature**	**Date**
(Head/ Designee - Production)		
(Head/ Designee - Quality control)		

Approved By	**Signature**	**Date**
(Head/ Designee - Quality Assurance		

2.0 OBJECTIVE:

Objective of hold time study is to establish the storage time of the respective bulk finished/ in-process material/ product with documented evidence.

3.0 SCOPE:

This protocol is applicable for hold time study of Binder solution, blend, uncoated tablets manufactured at .....

4.0 RESPONSIBILITY:

QUALITY ASSURANCE:

- Preparation, Execution & reviewing the protocol.
- Initiation of hold time sample request cum report.
- Collection of hold time samples as per hold time study protocol.
- Reviewing the QC result and draw conclusion.
- Preparation of hold time study summary report.

QUALITY CONTROL:

- Analysis of hold time samples.
- Review of hold time study protocol and summary report.

PRODUCTION:

- Review of hold time study protocol and summary report.
- Destruction of remaining hold time sample stored at manufacturing area.

5.0 Introduction:

Hold time Study of Product Telmisartan-40 shall be conducted to establish the time limits for holding the materials at different stages of production to ensure that the quality of the product does not get impacted during the hold time.

6.0 Procedure:

6.1 Study plan:

6.1.1 Product Details under Hold Time Study:

S.No.	Product Name	Batch No.	Batch Size	MFG. Date	EXP. Date
1					
2					
3					

6.1.2 Frequency/Reason of study:

Frequency/Reason	Tick mark the applicable option	No. of Batches to be kept under study	Justification for No. of batches selected if less than 3 batches
New product (New/ Transferred)			
Change in Manufacturing Formula components and composition			
Change in Manufacturing Procedure			
Change in batch size (More than 10 times)			
Change of Critical Manufacturing Equipment in Manufacturing Procedure			
Change in Active Source Supplier			
Change in In-process container/In-process storage conditions			
Change in critical specifications of the in-process stage			
Significant change in the existing manufacturing process			
Change in Storage condition			
Change in source of Key Raw material			

6.2 Environment conditions:

6.2.1 Storage area/condition:

6.2.1.1 Store the sample of hold time study at a temperature NMT 25^0C and Relative humidity NMT 60%.

6.2.2 Sample pack configuration:

6.2.2.1 For Sample of binder solution - Stainless steel (SS) container.
6.2.2.2 For sample of lubricated blend - Stainless steel (SS) container or in poly bag kept in High density polyethylene (HDPE) container as applicable.
6.2.2.3 For sample of compressed tablet - Poly bag kept in HDPE container.

6.3 Sampling method, Sample quantities and Sampling frequency (if any):

6.3.1 Sampling method:

6.3.1.1 Hold time sample shall be collected by IPQA person.
6.3.1.2 Store the hold-time samples in the same pack as is used in production unless the pack is exceptionally large, in which case one that is equivalent (constructed of the same material and using the same closure system as the production packaging system) may be used.
6.3.1.3 Sampling shall be carried out in respective hold area by IPQA person as per Hold time sample collection request shall be initiated by QA as per specified scheduled time interval.
6.3.1.4 QA shall ensure availability, cleanliness of sampling bag, sampling tools, and sampling label before sampling activity.
6.3.1.5 Affix "HOLD TIME SAMPLE" label by on the sample poly bag or container in which the sample is to be collected.
6.3.1.6 Wear hand gloves, open the container and sample the required quantity as mentioned in the hold time study protocol. Container shall be closed and tagged back at respective place after completion of sampling.
6.3.1.7 Send the hold time sample along with the Hold time sample collection request to QC.
6.3.1.8 Hold time study sample of binder solution shall be collected in a sterile container and shall be sent to microbiology laboratory and sampling at defined intervals shall be done by the microbiologist and shall be recorded.

6.3.2 Sample quantities and Sampling frequency:
6.3.2.1 Sample shall be collected as per defined quantity mentioned in the protocol.
6.3.2.2 Sampling frequency shall be as per the defined frequency in the annexure for "HOLD TIME STUDY SAMPLING AND SCHEDULE".

6.3.2.3 Sampling Plan for Hold Time Study:

S.No.	Storage Time	Sampling intervals	Test Parameters	Quantity of Sample	Total quantity of sample
BINDER SOLUTION FOR GRANULATION					
1.	Refer Annexure for "HOLD TIME STUDY SAMPLING AND SCHEDULE"	**Total Interval: 05** (Initial, After 2 Hrs, 4Hrs, 12 Hrs. & 24 Hrs.)	a) Appearance b) Microbial Test	*20 gm for every testing interval	120 gm
LUBRICATED BLEND					
2.	Refer Annexure for "HOLD TIME STUDY SAMPLING AND SCHEDULE"	**Total Interval: 05** Initial, 15th day, 30th day, 45th day & 60th day	a) Particle size distribution b) Bulk density c) Tap density d) Assay e) Microbial Test	*120 gm for every testing interval (80 gm for chemical/Physical test and 40 gm for microbial test)	720 gm
COMPRESSED TABLETS					
3.	Refer Annexure for "HOLD TIME STUDY SAMPLING AND SCHEDULE"	**Total Interval: 06** Initial, 15th day, 30th day, 45th day, 60th day & 90th day	a) Description b) Hardness c) Thickness d) Friability e) Disintegration time f) Dissolution g) Assay h) Microbial test	*425 Nos. for every testing interval (225 Nos. For Chemical/ Physical test and 200 Nos. for microbial test	2550 Nos.

*** Contains additional sample quantity to repeat the test in case of failure as per QC specification.**

6.4 Method of analysis:

6.4.1 As per QC STP No.: _____.

_____.

_____.

7.0 Acceptance criteria:

As per QC specification No.: _____.

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8.0 Deviation/OOS/Change Control (if any):

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9.0 Result and Evaluation:

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10.0 Conclusion:

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11.0 Abbreviation:

Mfg.: Manufacturing

Exp.: Expiry

^{0} C: Degree Celsius

%: Percentage

SS: Stainless steel

HDPE: High density polyethylene

gm: Gram

STP: Standard test procedure

OOS: Out of specification

12.0 Revision History:

Version No.	Details of Revision
00	New

13.0 Attachment if any:

Attachment No.	Attachment Details